Transluminal recanalization, angioplasty and stenting in endovascular surgery: techniques and applications

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Introduction

When first introduced 30 years ago, percutaneous transluminal angioplasty was received by most vascular surgeons as a near-inconceivable, dramatic departure from established principles. Instead, albeit unrecognized at the time, the work of Dotter initially and Gruentzig a decade later signalled the dawning of a new era in angiology. The balloon catheter was created, and became the first sophisticated tool of the endovascular interventionist. It has been refined and improved considerably in recent years, and remains the most versatile and cost-efficient device for transluminal intervention. A myriad of 'advanced-generation' catheters and devices have been proposed and developed over the past 10 years. The majority of these have proven no better or worse than the Gruentzig balloon. Several of these techniques are undergoing clinical trials and their application can only be justified in such context.

Endovascular therapy (or surgery) is a relatively new subspecialty which concerns a group of devices and procedures,

both diagnostic and therapeutic, sharing in common their catheter-based nature. Access to the vascular lumen is usually attained percutaneously, but there are situations where an open surgical approach is preferable or necessary. Three techniques, namely angioplasty, stenting and thrombolysis are emerging as fundamental in the endovascular interventionist's armamentarium. Clinical indications are becoming clearer as experience accumulates and long-term results become available. Focal stenotic lesions in high-flow, large-calibre arteries carry the best prognosis following endovascular treatment. In selected instances, occlusions can also be recanalized successfully.

What follows is a description of the basic endovascular techniques which have proven most useful in the authors' 6-year experience with over 1000 therapeutic transluminal interventions.

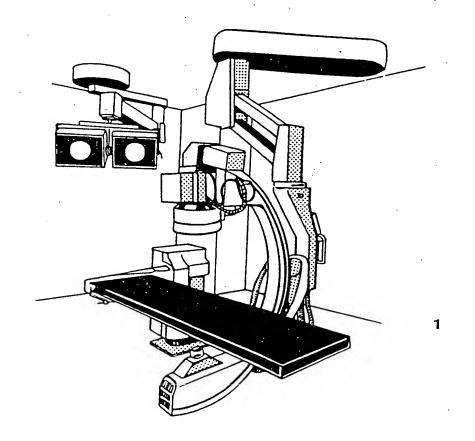
General considerations

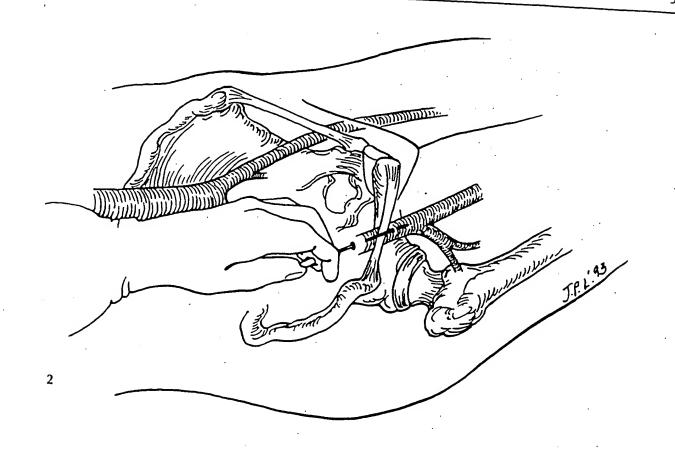
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With few exceptions, local infiltrative anaesthesia (at the puncture site) supplemented with intravenous sedation are utilized for all percutaneous repairs. Low molecular weight Dextran is infused at the rate of 40 ml/h during, and after the intervention for 24 hours. Anticoagulation with intravenous heparin is used in the course of all endovascular transluminal techniques, except when treating iliac stenotic lesions.

In endovascular surgery, aside from one's training and experience, nothing is more important than adequate X-ray

fluoroscopy and angiography. The concept of a vascular (or endovascular) suite has thus evolved: that is, a specially designed operating room equipped with a dedicated ceiling-mounted C-arm, and a carbon-fibre radiotranslucent operating table. The system, created by International Surgical Systems (Phoenix, Arizona, USA), is ideal for the performance of all types of endovascular catheter-based interventions, and any form of reconstructive vascular surgery requiring angiography (i.e. distal bypass grafting).

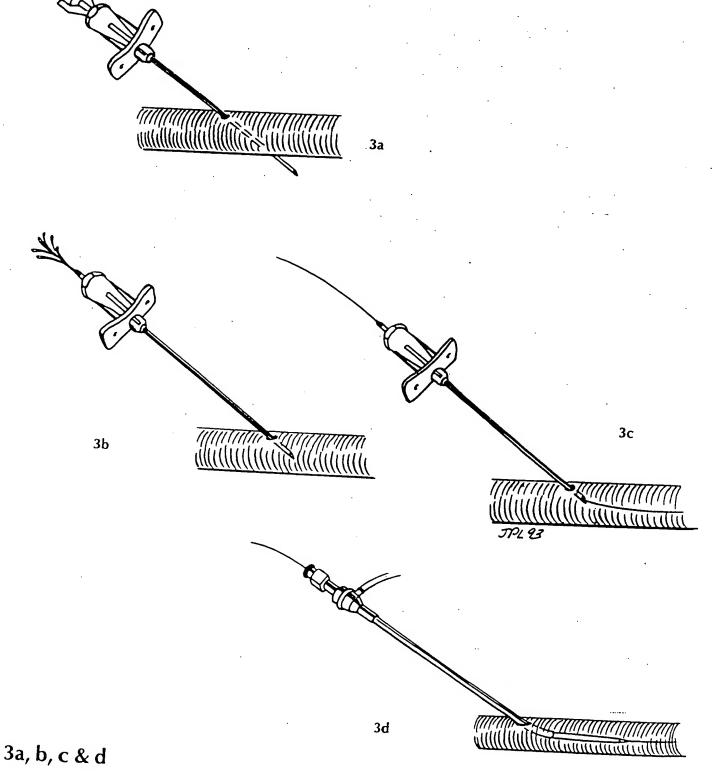




Percutaneous access to the vascular lumen

2

Percutaneous arterial puncture is performed with the Potts-Cournand needle. Femoral arterial puncture, whether antegrade or retrograde, should always be below the inguinal ligament. Suprainguinal puncture arterial holes cannot be compressed effectively after removal of the sheath, and troublesome bleeding may result.



Two-wall needle puncture is routine (a); the intraluminal position is secured and determined as the needle is gradually withdrawn (b). Single-wall puncture is advisable when anticipating the infusion of thrombolytic agents, and in the course of open surgical access. An angled, steerable guidewire is introduced through the needle and advanced under fluoro-

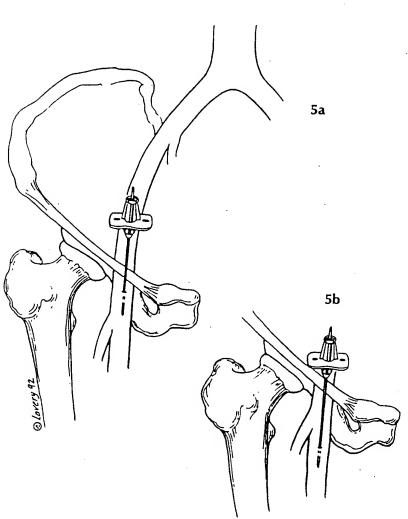
scopic control (c): a 0.035 inch Terumo glidewire is preferred in most instances. The needle is withdrawn, the skin opening enlarged a bit at the wire entry point with a number 11 blade, and the introducer sheath inserted over the wire into the vascular lumen (d). Proper positioning is confirmed angiofluoroscopically.

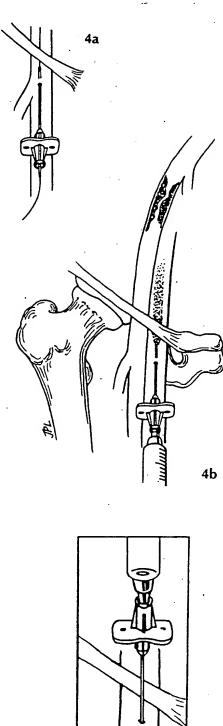
4a & b

Retrograde puncture of the common femoral artery is a simple technique even when the pulse is barely palpable or absent (a). Using the contrast-filled vein as reference may be useful (b). Note the infrainguinal course of the needle.

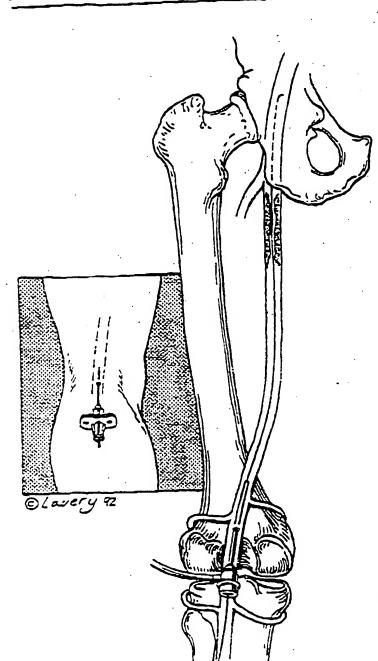
5a & b

Unlike the above-described, antegrade femoral puncture (a) is one of the most difficult skills to acquire in endovascular surgery. In a significant number of procedures, direct puncture of the superficial femoral artery is necessary and desirable when the femoral bifurcation lies high in the groin (b). 'Roadmapping' fluoroscopic capabilities are extremely helpful in performing this technique. A test-injection of radiocontrast material will serve to define the vascular anatomy and ascertain proper positioning of the needle before introduction of the wire and sheath (inset).





5 (inset)

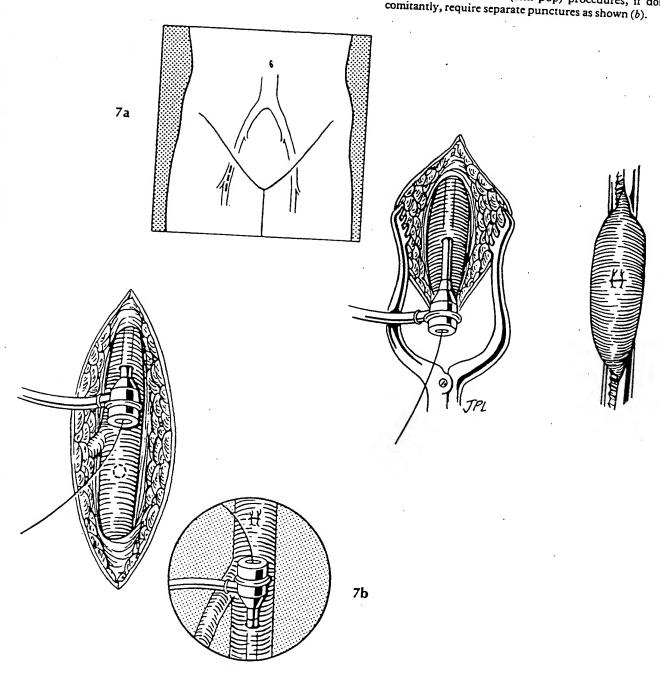


Percurencous retrograde puncture of the poplical arrery is another useful technique in selected circumstances. Proper case selection is paramount: only patients who can be demonstrated (on pre-procedure angiography) to have a relatively normal, large-calibre proximal poplitcal artery are eligible. Lesions in the proximal segment of the superficial femoral artery, and in the common femoral artery constitute the best applications of this technique. The patient is first positioned supine for the insertion of a small-calibre retrograde femoral sheath. The sheath is secured in place, and the patient turned proce. As radiocontrast material is injected proximally, the 'visualized' popliteal artery is punctured under 'direct vision' as seen on the fluoroscopy monitor. The subsequent steps are exectly the same as described for femoral access. Due to the potentially serious nature of bacmatomas in this location, Typ-Lewic heparin is not utilized in popliteal-access interventions.

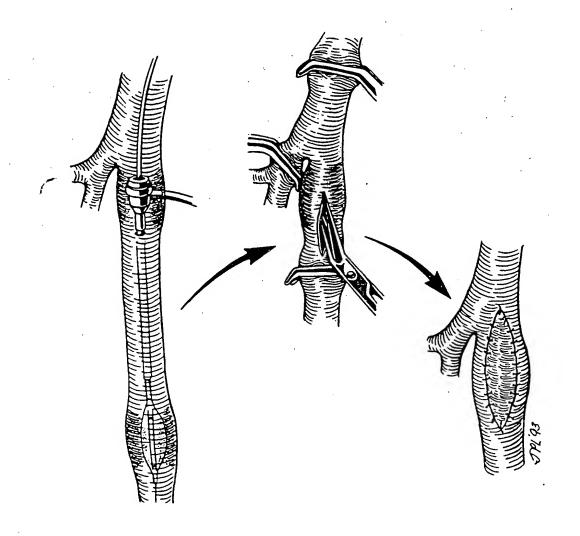
Open surgical access

7a & b

A femoral cutdown is employed infrequently, best indicate being significant obesity, and patients with dense, multi-scars in the groin. The exposure need not be wide: composesel control is not necessary. Aside from single-wall nee puncture, the technical steps are identical to those alrest described. Following withdrawal of the sheath, haemostasi secured with a single figure-of-eight suture while 'pinchi the segment between two DeBakey forceps (a). Upstre (iliac) and downstream (fem-pop) procedures, if done comitantly, require separate punctures as shown (b).



More complete exposure is needed when performing a combined surgical reconstruction.



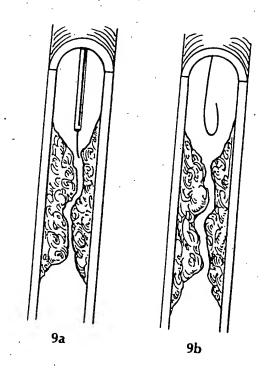
Transluminal navigation and lesion crossing

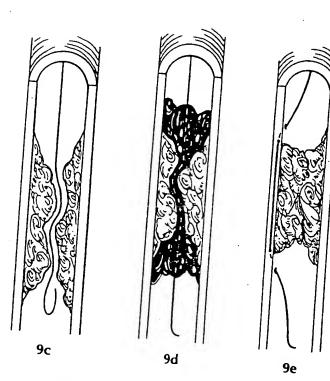
9a, b, c, d & e

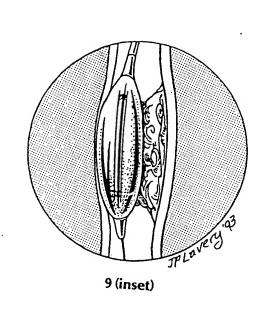
Advancement of the guidewire to the target lesion is an important component of all intraluminal procedures. Fluoroscopic control is required. The Terumo hydrophilic glidewire can cross most tight stenoses and even occlusions. When facing a difficult lesion, guiding and centring the wire with a straight angiographic catheter is a very useful manoeuvre to facilitate crossing (a) Allowing the wire to form a J is also quite helpful in this regard (b, c).

Total occlusions are often made up of much clot and an underlying flow-limiting atherosclerotic plaque. It is possible to traverse these occlusions much in the same way as in the case of stenoses (d). Clot that is easily penetrated by a wire can often be lusted successfully.

Subintimal recanalization is another possible route (e-inset). This is viewed as disadvantageous by most experts, but such opinion is not unanimous. No matter what the specific situation or technique of crossing, once the guidewire has been placed in its proper position, it must not be removed until the end of the procedure. This is a fundamental principle applicable to all transluminal interventions.







Haemostasis at puncture site

10

Care of the puncture site is a very important aspect in enc vascular surgery. Manual compression for 10-20 minutes necessary, performed by an experienced team member: tl manoeuvre should never be left to the uninitiated. When sy temic heparin in full doses has been administered, it is adv able to leave the sheath in place for 45-60 minutes, when it removed in the recovery room. We have recently found t Femostop device to be extremely helpful and now use

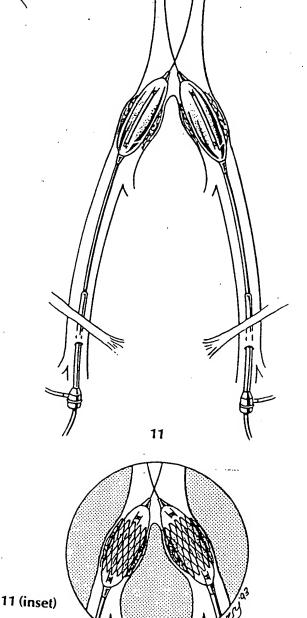
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Balloon angioplasty

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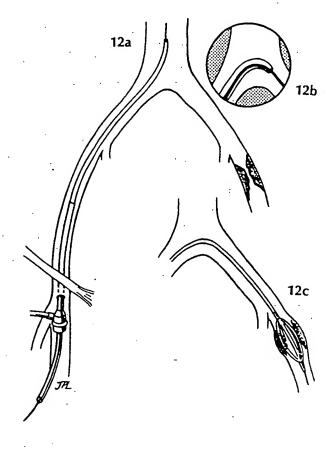
The Gruentzig balloon catheter remains the essential tool for endovascular intervention. Recent refinements of significance include improved trackability, lower profile and smaller-size catheters. In nearly every instance, 5 French catheters can now be utilized to dilate lesions in the lower extremities and other territories. Controversy persists regarding the duration of balloon inflation, and whether use of a pressure-gauge inflator is any better than a simple syringe. Balloon sizing is important and, at times, crucial. Overdilation and stretching of the vessel wall beyond its normal diameter is of little practical value, except - perhaps - during implantation of a balloonexpandable stent. Moreover, balloon-induced vessel rupture is a rare but not unknown complication. The subclavian and renal arteries are especially delicate vessels in this regard. When in doubt, it is best to 'undersize' a little and then dilate

Iliac angioplasty is the most successful endovascular procedure. The 'kissing-balloon' technique is a useful modification in cases of aortic bifurcation 'spill-over' lesions involving both iliac artery ostia; stents are frequently added at present (inset). While a 'good angiographic result' is a desirable outcome, the complete obliteration of translesional pressure gradients constitutes the most important therapeutic endpoint in



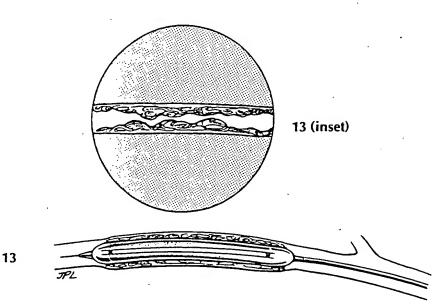
12a, b & c

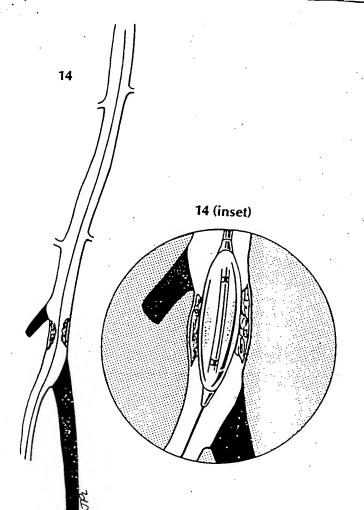
The cross-over (over-the-hump) approach (a, b, c) is a useful alternative in some situations such as mid and distal external iliac artery lesions (too close to where the ipsilateral puncture site would be), common femoral artery stenoses, and other iliac artery lesions resistant to conventional retrograde crossing. This approach is also preferred for preliminary thrombolysis of total occlusions. The technique involves the introduction of a curved catheter into the aorta, passed over an Amplatz superstiff wire. The wire is then withdrawn allowing the curve to re-form, and engage the contralateral iliac ostium as the catheter is pulled down while injecting small amounts of radiocontrast material. A standard wire is then introduced and passed downstream the opposite iliac system.



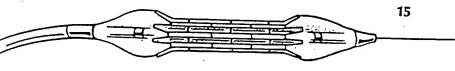
13

Long, 10 cm balloons are often necessary for angioplasty of the superficial femoral artery. Here again, lower profile, ultrathin catheters are preferred.





Balloon angioplasty of the small tibial-peroneal vessels is infrequently performed. The technique can be clinically beneficial in highly selected instances of focal lesions, especially those affecting the proximal calf vessels. One typical situation is illustrated: patients (usually diabetic) with occlusion of both tibial arteries, and single-vessel run-off via the peroneal artery. Angioplasty of a flow-limiting focal lesion in the tibioperoneal trunk or peroneal artery is likely to improve distal flow sufficiently as to promote healing of an ulcer or minoramputation site. Long-term patency is relatively unimportant once complete skin coverage has been obtained at the foot. Small-vessel angioplasty should only be attempted by experienced interventionists. Potential technical complications can easily lead to critical limb ischaemia and the need for a difficult distal bypass operation. Full anticoagulation with heparin is mandatory. It is also helpful to prevent frequent vasospastic responses with the administration of intra-arterial nitroglycerine in increments of 100 μ g.



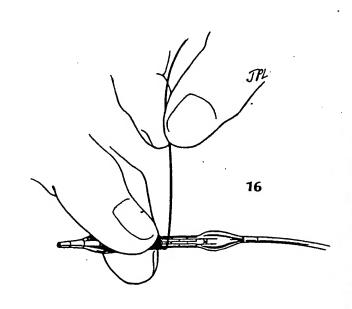
Stents

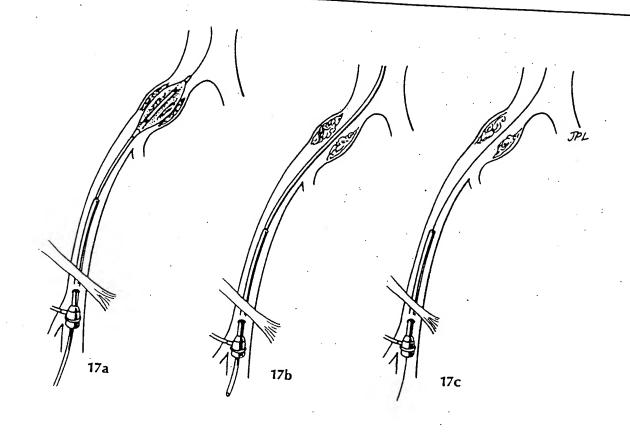
15 & 16

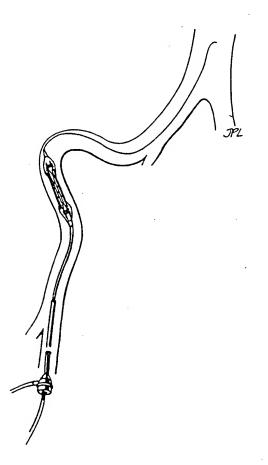
Stenting as an adjunct to angioplasty is a practically useful technique capable of preventing or correcting the mechanical problems associated with conventional balloon dilatation. Dissections, deep fissures into the media, and intimal flaps can all be neatly smoothed out and tacked down with implantation of an intravascular stent.

The Palmaz device (15) is a balloon-expandable stent with which we have had a great deal of experience beginning in 1989. Secure mounting of the stent on an appropriate balloon is paramount. A simple personal technical modification is shown (16). Nowadays, manufacturer-premounted stents are available.

While indications and notions regarding clinical benefit continue to evolve, a number of well-established principles can be enunciated.





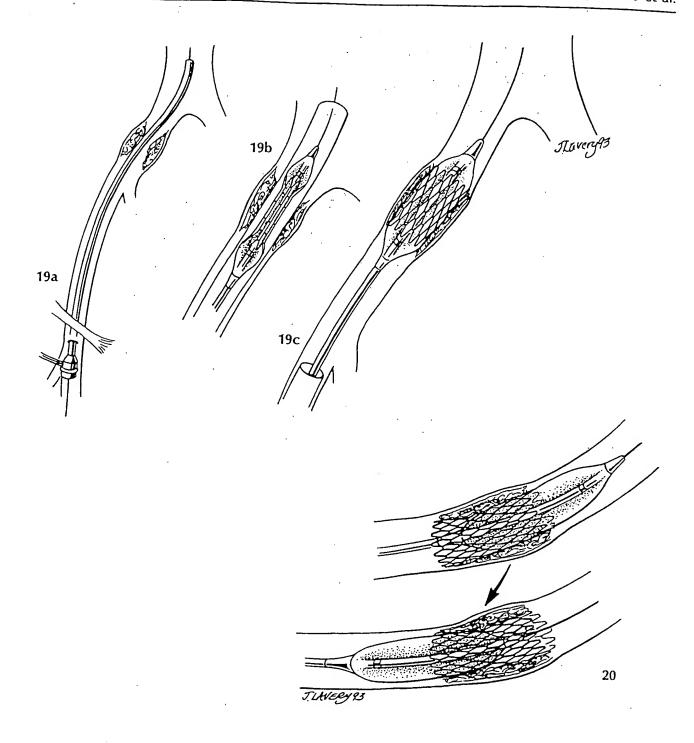


17a, b & c

'Standard' iliac artery stenting involves, first, preliminary conventional balloon angioplasty (predilatation) (a). Angiographic control at this juncture must rule out extravasation of contrast, for this constitutes an absolute contraindication to stent implantation. The standard guidewire is then exchanged for an Amplatz superstiff wire with the aid of a small (4–6 French) angiographic ('exchange') catheter (b, c). This is an important technical step designed to provide a firm track on which to advance the rigid stent. Moreover, with such stiff wire one can 'straighten' moderately tortuous iliac arteries.

18

Severe tortuosity and angulation, however, preclude stenting with this device: it is the second contraindication.



19a, b & c

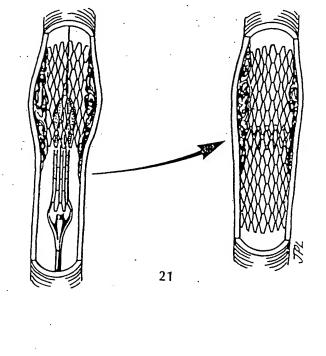
The next step involves introduction of the special long sheath, whose internal end should be positioned within the aortic lumen (a). This sheath (9 French in diameter) serves as a protective conduit for insertion and advancement of the stent mounted on the angioplasty (b). Once the stent has been positioned exactly where desired (under fluoroscopy), the sheath is pulled down to allow unimpeded balloon inflation with full expansion of the stent and incrustation into the vessel wall (c).

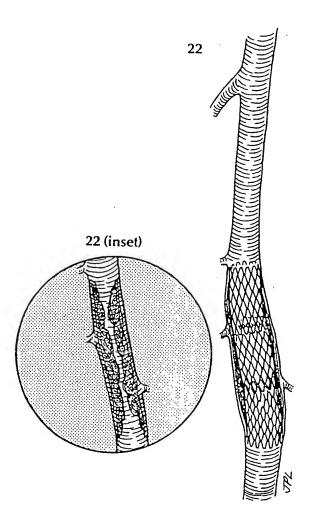
20

On occasion, it is advisable to effect two further balloon inflations at either end of the stent to ensure optimal deployment.

If more than one stent is deployed, the devices should be imbricated over 20% of their lengths, beginning with the most distal (from the introducer) and proceeding proximally.

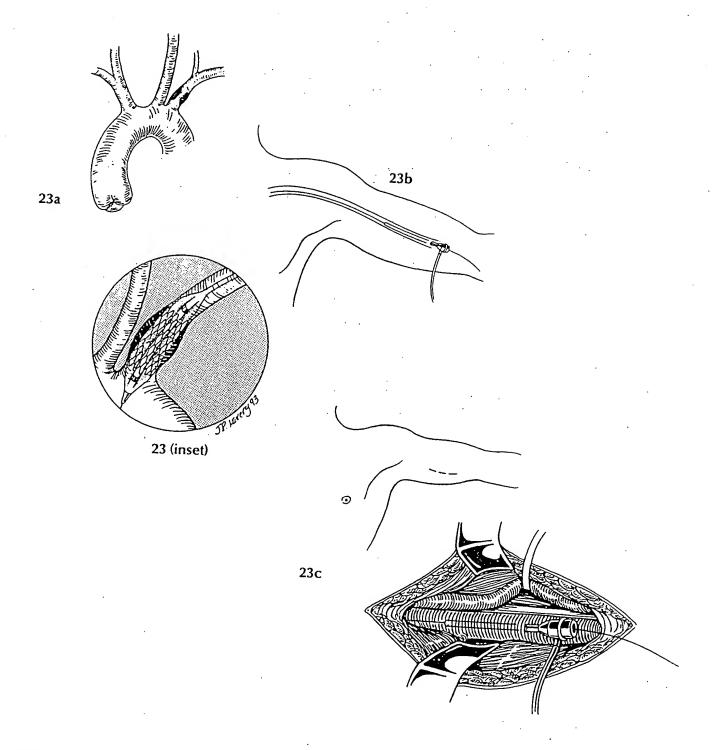
A modified simpler technique has evolved more recently. It consists of primary stenting, without pre-dilation, and utilizing a conventional 7 French short introducer sheath. These modifications are not recommended to the inexperienced. However, the availability of low-profile, pre-mounted stents have made these changes logical and quite safe. Omitting the preliminary angioplasty can be troublesome, though. One must learn to distinguish those lesions which are heavily calcified and so hard that they are not amenable to balloon expansion, or likely to perforate the balloon upon inflation (see below). In addition, extremely tight stenoses may not easily be crossed with a balloon/stent catheter: it pays to be cautious and predilate in all such circumstances.





22

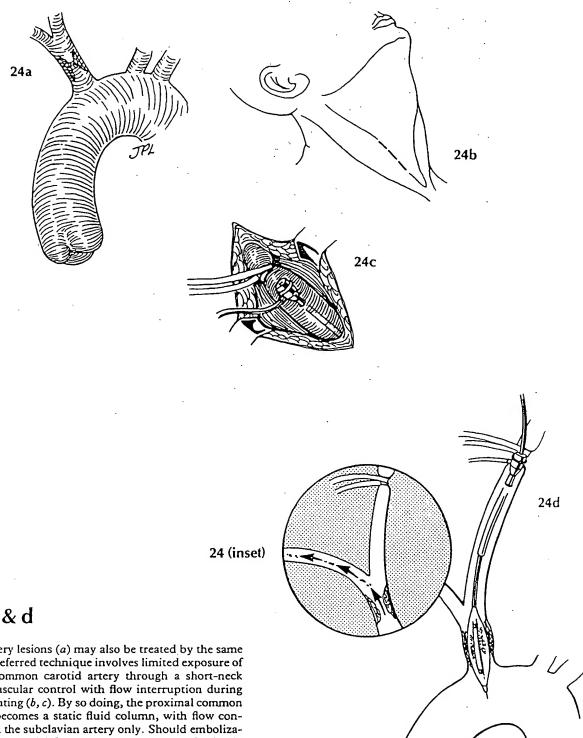
Stenting of the superficial femoral and popliteal arteries has yielded results which are much inferior to those obtained in the iliac system. In fact, it may not be any better than conventional balloon angioplasty. It is only in selected lesions and circumstances that stenting can be justified for those segments. The access is the same as with simple angioplasty. Multiple stents are often needed. Prolonged anticoagulation with warfarin may improve mid/long-term results for those patients.



23a, b & c

Focal lesions of the proximal subclavian artery (a) lend themselves well to endovascular therapy. Balloon angioplasty, with or without stenting, is rapidly becoming an important therapeutic alternative for these patients. Retrograde access through the brachial artery is preferred. Although percutaneous puncture (b) is quite simple, the potential for serious peripheral nerve complications make it less attractive. Open

surgical approach requires a small incision and local anzerthesia only (c). Direct and indirect (haematoma-induced), nerve injury can be avoided reliably. Markedly curved subclavian arteries can be very difficult for advancement and deployment of the Palmaz device; simple angioplasty, or a more flexible stent (i.e. wallstent) may be a better choice in such instances.



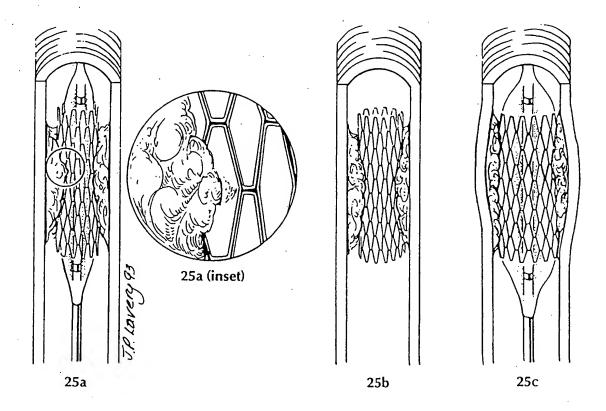
24a, b, c & d

Innominate artery lesions (a) may also be treated by the same method. Our preferred technique involves limited exposure of the proximal common carotid artery through a short-neck incision, and vascular control with flow interruption during angioplasty/stenting (b, c). By so doing, the proximal common carotid artery becomes a static fluid column, with flow continuing through the subclavian artery only. Should embolization occur, the potential for serious consequences is clearly diminished (d, inset).

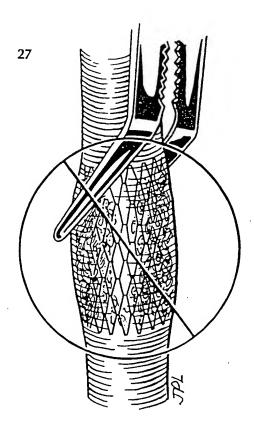
Problems and troubleshooting

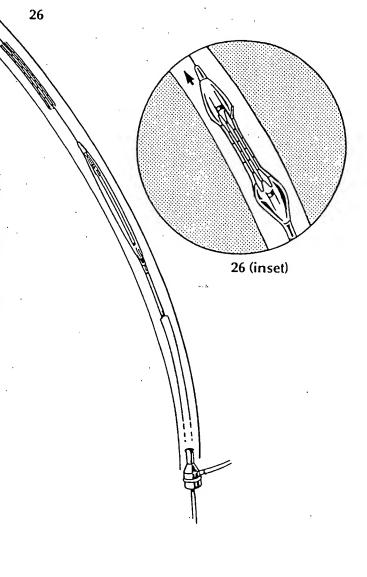
25a, b & c

Heavily calcified lesions, with intraluminal spicules and rough edges may pose a serious problem if the balloon is pierced halfway through inflation (a, inset), leaving an incompletely expanded stent (b). The device is fortunately often anchored enough, albeit precariously, as to allow exchange for a new balloon which will – hopefully – complete deployment (c). On occasion, it is possible to forcibly inflate the balloon for full expansion in spite of the leak. Use of the angiography power injector may also be a useful manoeuvre to effect full inflation of the ruptured balloon.



It has happened that the stent becomes detached from the balloon during initial transluminal navigation. Retrieval involves withdrawal of the balloon, and insertion of a smaller angioplasty catheter, perhaps of the coronary type. Such balloon should be able to re-enter the stent, and after being inflated a little, achieve better attachment of the stent which can now be carried upstream on the balloon (inset). Partial deployment is effected with this small balloon at the desired location, and then a larger balloon will complete full expansion. The other alternative, which may have prevented such incident in the first place, involves the introduction of a long sheath as shown in Illustration 19a. Once the stent is within it, they can both be extracted together.





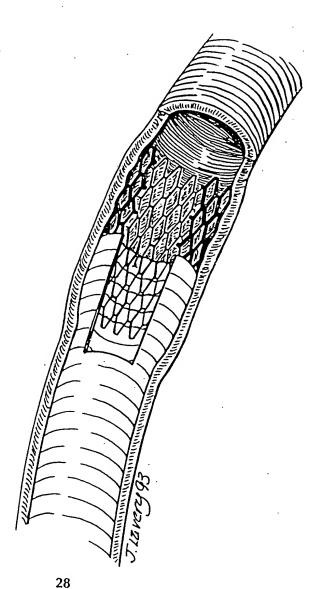
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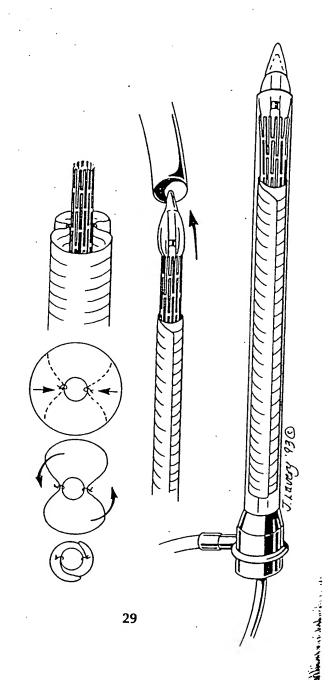
Finally, it must be realized that a previously stented vessel segment cannot be clamped or repaired directly. If surgical reconstruction is necessary, exclusion/bypass or replacement are the better alternatives.

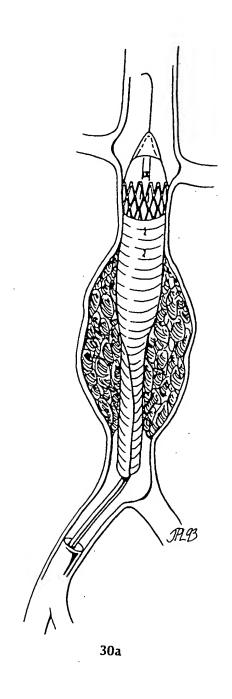
Endovascular grafting

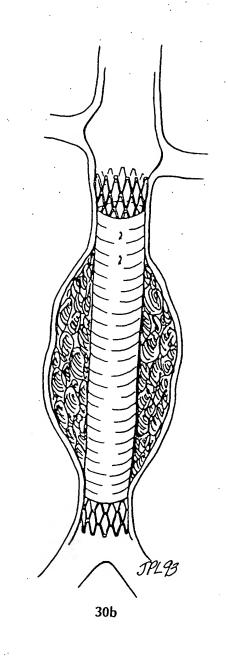
28 & 29

The use of stents to attach endoluminal fabric grafts is an evolving new horizon for this technology (28). Its most immediate and exciting application is to achieve transluminal exclusion of aortic aneurysms as championed by Parodi. Configuration of the stent-graft device is as illustrated (29). The entire delivery sheath with its assembled stent-graft mounted on a balloon catheter is tracked over the wire via retrograde transluminal approach after introduction through a femoral arteriotomy. The size and relative rigidity of the device (18 French presently) is an important limitation in cases of small and tortuous iliac arteries.





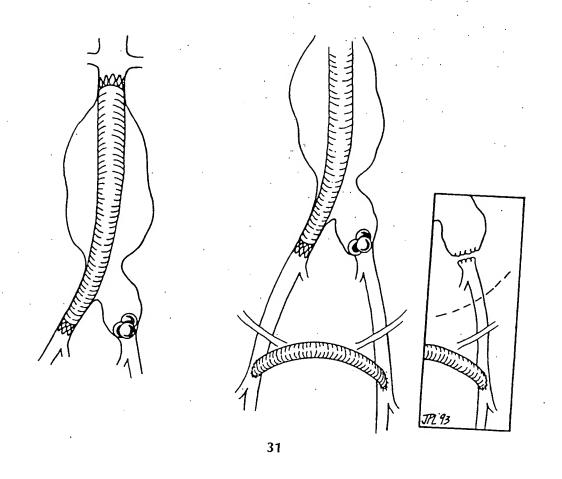




30a & b, 31

The final endoluminal graft configuration is either aorto-aortic (30a,b) or aorto-iliac unilateral utilizing a tapered prosthesis, and then a cross-over femoral-femoral bypass. Contralateral exclusion of the iliac system is necessary in the latter, either by surgical interruption or transluminally detached balloons (31). Endovascular grafting with this and other devices

will have important future applications beyond aneurysm exclusion: internal (transluminal) bypass, obliteration of arterio-venous communications, aortic dissections and others. To date, more than 100 endovascular grafting procedures have been performed by various investigators around the world.



Acknowledgement

We would like to thank Joyce P. Lavery, MFA for all the fine drawings in this chapter.

References

- Criado, F. J., Queral, L. A., Patten, P. et al. (1993). The role of endovascular therapy in lower extremity revascularization: lessons learned and current strategies. *International Angiography* 12, 221.
- Dotter, C. T. and Judkins, M. P. (1964). Transluminal treatment of arteriosclerotic obstruction: description of a new technique and a preliminary report of its application. Circulation 30, 654.
- Gruntzig, A. and Hopff, H. (1974). Perkutane rekanalization chronischer arterieller: verschlusse miteinem nellen dilatation—skatheter modification der dotterechnik. Disch Med Wochenscher 9, 2502.
- Johnston, K. W. (1992) Factors that influence the outcome of aortoiliac and femoropopliteal percutaneous transluminal angioplasty. Surgical Clinics of North America 72, 843.
- Parodi, J. C., Criado, F. J., Barone, H. D. et al. (1994). Endoluminal aortic aneurysm repair utilizing the Parodi balloon-expandable stent-graft device: a progress report. Annals of Vascular Surgery in press).
- Palmaz, J. C., Laborde, J. C., Rivera, F. J. et al. (1992). Stenting of the iliac arteries with the palmaz stent: experience from a multicenter trial. Cardiovascular Interventional Radiology 15, 291.
- Weller, B. F. (1989). "Crackers, breakers, stretchers, drillers, scrapers, shavers, burners, welders, and melters"—the future treatment of atherosclerotic coronary artery disease? A clinical-morphologic assessment. Journal of the American College of Cardiologists 13, 969.

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